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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,740	06/23/2000	Markus Pompejus	BGI-126CP	1632
959	7590	01/13/2005	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 01/13/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/602,740

Applicant(s)

POMPEJUS ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,9-14,17-29,31-33 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 18-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,9-14,17,25-29,31-33 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/1/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>to Applicant</u> . |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on April 1, 2004), Applicants filed a response and amendment received on October 4, 2004. Said amendment amended Claims 5, 12, and 17 and added new Claim 39. Thus, Claims 1, 4-6, 9-14, 17-29, 31-33 and 39 are pending in the instant Office action.

Election

2. Claims 1, 4-6, 9-14, 17-29, 31-33 and 39 are pending. Claims 18-24 are drawn to non-elected invention(s) not subject to rejoinder with the elected claims. Claims 1, 4-6, 9-14, 17, 25-29, 31-33 and 39 will be examined herein.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/141,031, filed on June 25, 1999, 60/143,208, filed on July 9, 1999, and 60/151,572, filed on August 31, 1999.

Also as previously noted, the Examiner reiterated an inability to identify support for SEQ ID NOs:1/2 in said provisional applications. Thus, the instant claims are granted the benefit of priority to June 23, 2000, the filing date of the instant application. If the Examiner is in error, Applicants must cite clear support (page of the provisional application) where SEQ ID NOs:1/2 can be found.

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4. As previously noted, no certified copies for the foreign priority documents claimed have been received. Without certified copies of the foreign applications whose foreign priority has been requested (27 German applications), priority cannot be granted. Applicants have noted that certified copies would be filed upon issuance of a patent. Thus, foreign priority is herein **NOT** granted. Acknowledgment is made of applicant's claim for foreign priority based on applications (27 total) filed in Germany.

Claim Objections

5. Claim 27 is objected to under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim depends from two different claims not in the alternative. See M.P.E.P. § 608.01(n). Correction is required.

6. Claim 27 is noted for containing "the step of transfecting" wherein the remainder of the claims is drawn to ***transformed*** bacteria. Applicant's attention is drawn to this fact, perhaps warranting amendment.

7. Claim 33 is objected to for containing improper Markush language. The phrase "amino acid is drawn from the group consisting of" should be ---amino acid is selected from the group consisting of--- for proper Markush language. Correction is required.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

8. Previous rejection of Claims 5 and 9 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "naturally occurring" is withdrawn by virtue of Applicant's amendment removing said phrase.

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9. Previous rejection of Claims 13-14 under 35 U.S.C. § 112, second paragraph, as being indefinite because Claim 12 used the term “transfected” while Claims 13-14 were drawn to bacteria (which are transformed) is withdrawn by virtue of Applicant’s amendment to Claim 12.
10. Previous rejection of Claim 17 under 35 U.S.C. § 112, second paragraph, as being indefinite for the “produced” polypeptide is withdrawn by virtue of Applicant’s amendment.
11. Previous rejection of Claims 5 and 9 under 35 U.S.C. § 112, first paragraph, written description, for allelic variants, is withdrawn by virtue of Applicant’s amendment.

New or Maintained - Claim Rejections - 35 U.S.C. § 112

12. Claims 1 and 5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 1, the phrase “a complement thereof” (emphasis added) is unclear because only one complement of SEQ ID NO:1 is known and the article ---a--- indicates more than one. The Examiner suggests ---the complement thereof---.

Similarly, in Claim 5, the phrase “the complement of a nucleic acid molecule consisting of SEQ ID NO:1” (emphasis added) is unclear for the same reasons. Clarification is required.

13. Claim 6 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear which “complement” is intended. The Examiner suggests the following language: ---comprising (a) a nucleotide sequence which has at least 90% identity with the nucleotide sequence of SEQ ID NO:1, wherein said nucleic acid molecule encodes a

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polypeptide having 6-phosphogluconolactonase activity, or (b) the complement of (a)--- for clarity. Clarification is required.

14. Previous rejection of Claims 5, 6, and 9 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained and amended to include Claim 17 and new Claim 39. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the Examiner previously noted the 90% identity was enabled; however, the instant rejection cites that such breadth is not enabled. The Examiner agrees that the prosecution of enablement has changed; this is due to the Examiner's reconsideration of the claims at this stage of prosecution, which is required at every stage of prosecution by 37 C.F.R. § 1.112. Thus, it is the present position that 90% and/or 95% identity to SEQ ID NO:1 is not enabled.

Applicant argues that the few sequences of 6-phosphogluconolactonases in the art (ass IDS filed November 1, 2004) enable the claimed invention; this is not the case. These other disclosures of 6-phosphogluconolactonases "do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotides within the scope of the claims because the ability to find a 6-phosphogluconolactonase gene, which is structurally related to SEQ ID NO:1, is not equivalent to the ability to make a 6-phosphogluconolactonase gene as required by the statute (i.e., "make and use")" (see previous Office action). No alignment showing conserved residues is shown in the prior art. As noted by Applicant:

"Based on Applicants' identification of the instant *Corynebacterium glutamicum* gene and its function, the critical domains for 6-phosphogluconolactonase activity **may** have been determined by one skilled in the art, without undue experimentation. Indeed, one skilled in the art **may** have determined the conserved domains among the known sequences by simple BLAST techniques well known in the art" (emphasis added).

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With such uncertainty about how the functionality of the claimed gene is discerned, it is unclear how the skilled artisan could accomplish the same without undue experimentation. Moreover, what Applicant's representative describes is the ability to identify a discovered sequence as a 6-phosphogluconolactonase gene and not the ability to make a 6-phosphogluconolactonase gene as required by the statute. Thus, the instant rejection is maintained and applied to Claim 17 and new Claim 39 for the reasons previously of record.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1, 4-6, 9-14, 17, 25-29, 31-33, and 39 are rejected under 35 U.S.C. § 102(e) as being anticipated by Dunican *et al.* (USPN 6,797,509). The instant claims are drawn to SEQ ID NO:1, related products and methods.

Dunican *et al.* teach a 6995 base pair DNA sequence comprising SEQ ID NO:1 from 6093-6920 (see attached alignment). Dunican *et al.* also teach using said DNA sequence in the production of amino acids, in particular lysine, threonine, and tryptophan, after having been transformed into *C. glutamicum*, for example (see abstract, column 1, lines 10-14, and column 3, lines 65-67). The Examiner notes that such teachings are supported in the priority document 60/142915 filed on July 9, 1999 by Dunican *et al.*

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The applied reference has a common assignee (Degussa) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. § 102(e). This rejection under 35 U.S.C. § 102(e) might be overcome either by a showing under 37 C.F.R. § 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 C.F.R. § 1.131.

Summary of Pending Issues

16. The following is a summary of the issues pending in the instant application:
- a) Claim 27 stands objected to under 37 C.F.R. § 1.75(c) as being in improper dependent form.
 - b) Claim 33 stands objected to for containing improper Markush language.
 - c) Claims 1 and 5 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the unclear phrases “a complement thereof” (emphasis added) and “the complement of a nucleic acid molecule consisting of SEQ ID NO:1” (emphasis added).
 - d) Claim 6 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for which “complement” is intended.
 - e) Claims 5, 6, 9, 17, and 39 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
 - f) Claims 1, 4-6, 9-14, 17, 25-29, 31-33, and 39 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Dunican *et al.* (USPN 6,797,509).

Conclusion

17. No claims are allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant office action is NON-FINAL based on the new grounds of rejection set forth herein.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931.

The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

January 7, 2005

to Applicant

US-09-531-266-1

; Sequence 1, Application US/09531266
; GENERAL INFORMATION:
; APPLICANT: DUNICAN, L.K.
; APPLICANT: MCCORMACK, ASHLING
; APPLICANT: STAPELTON, CLIONA
; APPLICANT: BURKE, KEVIN
; APPLICANT: MOCKEL, BETTINA
; TITLE OF INVENTION: NEW NUCLEOTIDE SEQUENCES WHICH CODE FOR THE TAL GENE
; FILE REFERENCE: MAS/21123/258100
; CURRENT APPLICATION NUMBER: US/09/531,266
; CURRENT FILING DATE: 2000-03-20
; PRIOR APPLICATION NUMBER: 60/142,915
; PRIOR FILING DATE: 1999-07-09
; NUMBER OF SEQ ID NOS: 6
; SOFTWARE: PatentIn Ver. 2.1
; SEQ ID NO 1
; LENGTH: 6995
; TYPE: DNA
; ORGANISM: Corynebacterium glutamicum
; FEATURE:
; NAME/KEY: CDS
; LOCATION: (2471)..(3550)
; OTHER INFORMATION: tal-Gen
US-09-531-266-1

Query Match 100.0%; Score 828; DB 20; Length 6995;
Best Local Similarity 100.0%; Pred. No. 2.5e-218;
Matches 828; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy	1	GAGGAGCTTCGCCACATGGATCCAGATTG	GGGCTACCAGCACGCAC	TATCCGGCTTGTCC	60
Db	6093	GAGGAGCTTCGCCACATGGATCCAGATTG	GGGCTACCAGCACGCAC	TATCCGGCTTGTCC	6152
Qy	61	AGCGTCAAGCTGGAAACCGTCTAAGGAGAA	ATAACA	CTATGGTTGATGTAGTACGCGC	120
Db	6153	AGCGTCAAGCTGGAAACCGTCTAAGGAGAA	ATAACA	CTATGGTTGATGTAGTACGCGC	6212
Qy	121	ACGCGATACTGAAGATTTGGTTGCACAGGCT	GCCTCCAAATTCATTGAGGTTGTTGAAGC	180	
Db	6213	ACGCGATACTGAAGATTTGGTTGCACAGGCT	GCCTCCAAATTCATTGAGGTTGTTGAAGC	6272	
Qy	181	AGCAACTGCCAATAATGGCACC	GCACAGGTAGTGCTCACC	GGTGGCGCCGGCATCAA	240
Db	6273	AGCAACTGCCAATAATGGCACC	GCACAGGTAGTGCTCACC	GGTGGCGCCGGCATCAA	6332
Qy	241	GTTGCTGGAAAAGCTCAGCGTTGATGCGGCT	GACCTGCCTGGGATCGCATT	CATGTGTT	300
Db	6333	GTTGCTGGAAAAGCTCAGCGTTGATGCGGCT	GACCTGCCTGGGATCGCATT	CATGTGTT	6392
Qy	301	CTTCGGCGATGAGCGCAATGTCCCTGT	CAGTGATTCTGAGTCCAATGAGGGCCAGGCTCG	360	
Db	6393	CTTCGGCGATGAGCGCAATGTCCCTGT	CAGTGATTCTGAGTCCAATGAGGGCCAGGCTCG	6452	
Qy	361	TGAGGCACTGTTGTCCAAGGTTTCTATCCCT	GAAGCCAACATTCACGGATATGGTCTCGG	420	
Db	6453	TGAGGCACTGTTGTCCAAGGTTTCTATCCCT	GAAGCCAACATTCACGGATATGGTCTCGG	6512	

Qy	421	CGACGTAGATCTTGCAGAGGCAGCCCGCGCTTACGAAGCTGTGTTGGATGAATTTCGCACC	480
Db	6513	CGACGTAGATCTTGCAGAGGCAGCCCGCGCTTACGAAGCTGTGTTGGATGAATTTCGCACC	6572
Qy	481	AAACGGCTTTGATCTTACCTGCTCGGCATGGGTGGCGAAGGCCATATCAACTCCCTGTT	540
Db	6573	AAACGGCTTTGATCTTACCTGCTCGGCATGGGTGGCGAAGGCCATATCAACTCCCTGTT	6632
Qy	541	CCCTCACACCGATGCAGTCAAGGAATCCTCCGCAAAGGTCATCGCGGTGTTTGATTCCCC	600
Db	6633	CCCTCACACCGATGCAGTCAAGGAATCCTCCGCAAAGGTCATCGCGGTGTTTGATTCCCC	6692
Qy	601	TAAGCCTCCTTCAGAGCGTGCAACTCTAACCCCTTCCTGCGGTTCAC'TCCGCAAAGCGCGT	660
Db	6693	TAAGCCTCCTTCAGAGCGTGCAACTCTAACCCCTTCCTGCGGTTCAC'TCCGCAAAGCGCGT	6752
Qy	661	GTGGTTTGCTGGTTTCTGGTGCGGAGAAGGCTGAGGCAGCTGCGGCGATCGTCAACGGTGA	720
Db	6753	GTGGTTTGCTGGTTTCTGGTGCGGAGAAGGCTGAGGCAGCTGCGGCGATCGTCAACGGTGA	6812
Qy	721	GCCTGCTGTTGAGTGGCCTGCTGCTGGAGCTACCGGATCTGAGGAAACGGTATTGTTCTT	780
Db	6813	GCCTGCTGTTGAGTGGCCTGCTGCTGGAGCTACCGGATCTGAGGAAACGGTATTGTTCTT	6872
Qy	781	GGCTGATGATGCTGCAGGAAATCTCTAAGCAGCGCCAGCTCTAACAAG	828
Db	6873	GGCTGATGATGCTGCAGGAAATCTCTAAGCAGCGCCAGCTCTAACAAG	6920